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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,841	BOYLAN ET AL.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "47" (on page 12, paragraph 47) and "68" (on page 13, paragraph 52). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: In the section entitled "Brief Description of the Drawings" applicant has omitted a description of figure five. Applicant is required to amend the specification to include a brief description of each drawing or figure. See MPEP § 608.01(f).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 2, 4, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. (5,910,154) in view of Abrams et al. (5,341,818).** Tsugita et al. reference discloses the invention substantially as claimed, including a "self-expanding strut assembly" (54) including a nickel-titanium alloy (see Column 8, Lines 48-50) and a "filter element" (60) disposed on the strut assembly (see Figures 6A and 6B). However, Tsugita et al. reference does not disclose the nickel-titanium alloy contains a ternary element (platinum, palladium, or tantalum) and the alloy having a hysteresis curve with a loading plateau of 100-110 ksi and an unloading plateau of 55-100 ksi. Attention is drawn to Abrams et al. reference, which teaches a nickel-titanium alloy with a ternary element of platinum or palladium (see final paragraph of Column 6) with a hysteresis curve having a loading plateau of 110 ksi and an unloading plateau of

55 ksi (see Figure 2) to help provide an expanded strain range at very high stresses (see Column 7, Lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alloy with hysteresis characteristics as taught by Abrams et al. to create the strut assembly of Tsugita et al. reference to help provide an expanded strain range at very high stresses.

Regarding claim 1, Tsugita et al. reference discloses the strut assembly is capable of being self-expanding (see Column 12, Lines 28-41).

Regarding claim 2, the system of Tsugita et al. reference discloses a sheath at least partially covers the filter element when it is in it's collapsed configuration (see Column 12, Lines 28-30).

Regarding claim 4, the strut assembly of Tsugita et al. reference has a conical shape with a first base and the filter has a conical shape with a second base, and the bases are joined (see Figure 6A at Ref. Numeral 58, or see Figure 6B at Ref. Numeral 56). The bases are interpreted to be the tips of the strut assembly and the filter.

Regarding claim 6, the alloy of Abrams et al. reference has a transition temperature lower than human body temperature (see Column 5, Lines 15-18).

Regarding claim 7, the hysteresis curve of Abrams et al. reference (Figure 2) has a loading plateau of 110 ksi and an unloading plateau of 55 ksi. By simple math, this is a ratio of loading to unloading stresses of 2:1 (i.e. $\frac{110}{55} = \frac{2}{1} = 2:1$).

Regarding claim 8, the alloy of Abrams et al. reference exhibits superelasticity while inside the body (see Column 8, Lines 11-14).

4. **Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. (5,910,154) in view of Abrams et al. (5,341,818) as applied to claim 2 above, and further in view of Clark et al. (5,713,853).** Tsugita et al. reference, in combination with the alloy of Abrams et al. reference, discloses the invention substantially as claimed, including a "self-expanding strut assembly" (54) including a nickel-titanium alloy (from Abrams et al. reference), a "filter element" (60) disposed on the strut assembly, and a sheath at least partially covering the filter element (see Figures 6A and 6B). However, the combination of Tsugita et al. reference with Abrams et al. reference does not disclose that the assembly is cut from a tube with truncated diamond shape openings. Attention is drawn to Clark et al. reference, which teaches a shaft can be cut with a laser (see Column 11, Lines 25-26) to form the desired structure with accuracy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the strut members with the diamond shape pattern, as disclosed by Tsugita et al. reference and shown in Figures 6A-6B, by laser cutting, as taught by Clark et al. reference, to form the desired structure with accuracy.

5. **Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. (5,910,154) in view of Abrams et al. (5,341,818) as applied to claim 1 above, and further in view of Clark et al. (5,713,853).** Tsugita et al. reference, in combination with the alloy of Abrams et al. reference, discloses the invention substantially as claimed, including a "self-expanding strut assembly" (54) including a nickel-titanium alloy (from Abrams et al. reference) and a "filter element" (60) disposed on the strut assembly (see Figures 6A and 6B). However, the combination of Tsugita et

al. reference with Abrams et al. reference does not disclose that the assembly includes a pattern that is laser cut from a tube. Attention is drawn to Clark et al. reference, which teaches a shaft can be cut with a laser (see Column 11, Lines 25-26) to form the desired structure with accuracy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pattern the strut members, as disclosed by Tsugita et al. reference and shown in Figures 6A-6B, by laser cutting, as taught by Clark et al. reference, to form the desired structure with accuracy.

6. **Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. (5,910,154) in view of Abrams et al. (5,341,818).** Tsugita et al. reference discloses the invention substantially as claimed, including a "self-expanding strut assembly" (54) including a nickel-titanium alloy (see Column 8, Lines 48-50) and a "filter element" (60) disposed on the strut assembly (see Figures 6A and 6B). However, Tsugita et al. reference does not disclose the nickel-titanium alloy contains a ternary element (platinum, palladium, or tantalum) and the alloy having a small stress hysteresis with a ratio of loading to unloading stresses of between 2:1 and 1.1:1 and a loading plateau of 110 ksi. Attention is drawn to Abrams et al. reference, which teaches a nickel-titanium alloy with a ternary element of platinum or palladium (see final paragraph of Column 6) with a hysteresis curve having a loading plateau of 110 ksi and a loading to unloading stress ratio of 2:1 (see Figure 2) to help provide an expanded strain range at very high stresses (see Column 7, Lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alloy with hysteresis characteristics as taught by Abrams et al. to create the

strut assembly of Tsugita et al. reference to help provide an expanded strain range at very high stresses.

Regarding claim 9, Tsugita et al. reference discloses the strut assembly is capable of being self-expanding (see Column 12, Lines 28-41).

Regarding claim 10, the unloading plateau is 55 ksi (see Figure 2 of Abrams et al. reference).

Regarding claim 11, alloy of Abrams et al. reference used to create the strut assembly is Tsugita et al. reference is heat treated at about 500 degrees C (see Column 7, Lines 46-49).

7. **Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. (5,910,154) in view of Abrams et al. (5,341,818).** Tsugita et al. reference discloses the invention substantially as claimed, including a "self-expanding strut assembly" (54) including a superelastic alloy (see Column 8, Lines 48-50) and a "filter element" (60) disposed on the strut assembly (see Figures 6A and 6B). However, Tsugita et al. reference does not disclose the superelastic alloy contains a ternary element (platinum, palladium, or tantalum) and the alloy having a makeup of 30 to 52 atomic percent titanium, at least 38 atomic percent nickel, and up to 15 atomic percent of the ternary element, with the alloy having a characteristic hysteresis curve with a loading plateau of 110 ksi and an unloading plateau of 55 ksi. Attention is drawn to Abrams et al. reference, which teaches a nickel-titanium alloy with a ternary element of platinum or palladium with an atomic makeup of 30 to 52 atomic percent titanium, up to 10 percent of the ternary element, and the balance (between 38 and 60 atomic percent)

being nickel (see final paragraph of Column 6), and with a hysteresis curve having a loading plateau of 110 ksi and an unloading plateau of 55 ksi (see Figure 2) to help provide an expanded strain range at very high stresses (see Column 7, Lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alloy with hysteresis characteristics and atomic makeup as taught by Abrams et al. to create the strut assembly of Tsugita et al. reference to help provide an expanded strain range at very high stresses.

Regarding claim 12, Tsugita et al. reference discloses the strut assembly is capable of being self-expanding (see Column 12, Lines 28-41).

Regarding claim 13, the hysteresis curve of the alloy of Abrams et al. reference has an absolute Δy of 55 ksi. This is illustrates the difference between the loading an unloading plateaus as shown in the following equation:

- $\Delta y = 110ksi - 55ksi = 55ksi$

Regarding claim 14, the hysteresis curve of Abrams et al. reference (Figure 2) has a loading plateau of 110 ksi and an unloading plateau of 55 ksi. By simple math, this is a ratio of loading to unloading stresses of 2:1 (i.e. $\frac{110}{55} = \frac{2}{1} = 2:1$).

Regarding claim 15, the alloy of Abrams et al. reference is a shape-memory alloy (see Column 7, Lines 15-21).

Regarding claim 16, the alloy of Abrams et al. reference has a transition temperature lower than human body temperature (see Column 5, Lines 15-18). The human body temperature is typically considered 98.6 degrees F, which is the equivalent

to 37 degrees C, which is much lower than 45 degrees C as claimed by applicant in claim 16.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ryan Severson
October 12, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/15/06.